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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,960	11/09/2001	Walter J. Stevens	STAN-132CIP	5625
24353	7590	12/29/2003	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 200 MIDDLEFIELD RD SUITE 200 MENLO PARK, CA 94025			BAXTER, JESSICA R	
			ART UNIT	PAPER NUMBER
			3731	
			DATE MAILED: 12/29/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/010,960

Applicant(s)

STEVENS ET AL.

Examiner

Jessica R. Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Specification*

1. The abstract of the disclosure was objected to because the term "structural means" is used.

Correction is noted and the objection is withdrawn.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

~~The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.~~

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the first and second structural means are rigid and flexible.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, <sup>4</sup>~~2~~ 26, 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.

Patent No. 4,366,819 to Kaster.

Regarding claims 1, 5, 7, 9 and 25, Kaster discloses an anastomosis system comprising first (52) and second structural means (56), wherein each of said first and second structural means comprises a tubular region that terminates in a lip at one end (FIG. 9), and further wherein said first and second structural means are capable of assuming a nested configuration (FIG. 9).

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Regarding claims 2, 8, 16 and 26, Kaster discloses that the inner diameter of the tubular region of said second structural means (56) is greater than the outer diameter of the tubular region of said first structural means (FIG. 9). Kaster discloses that said first and second structural means are flexible (Column 10 lines 3-19).

Regarding claims 4 and 21, Kaster discloses that said first and second structural means are rigid (Column 10 lines 3-19).

~~Regarding claims 6 and 10, Kaster discloses that said first and second structural~~  
means are separate (Column 9 lines 53-60).

Regarding claim 11, Kaster discloses that each lip of said first and second structural means has a curvilinear configuration (FIG. 9).

Regarding claim 12, Kaster discloses that said curvilinear configuration of said lip of said first structural means is different from said curvilinear configuration of said lip of said second structural means (FIG. 9).

Regarding claim 13, Kaster discloses that the length of the tubular region of the second structural means is less than the length of the tubular structure of the first structural means (FIG. 9).

Regarding claim 14, Kaster discloses a vessel (60) inserted through first (52) and second structural means (56), wherein said first and second structural means each have a tubular region that terminates at one end in a lip (FIG. 9), and wherein said first and second structural means are capable of assuming a nested configuration (FIG. 9).

Regarding claims 14 and 15, Kaster discloses that the end of said vessel (vein 60) is everted over the distal surface and at least a portion of the proximal surface of the lip (lip 52g) of said first structural means (FIG. 9).

Regarding claims 17-19 and 28, Kaster discloses that the vessel is a naturally occurring vessel, a vascular vessel, or a synthetic vessel (Column 4 lines 62-68).

Regarding claim 22, Kaster discloses a method for performing an end-to-side anastomosis, said method comprising: (a) preparing an opening in a host vessel (hole 22a); (b) inserting into said opening the end of a prepared graft vessel having a graft vessel threaded through first and second structural means wherein each of said first and second structural means has a tubular region that terminates at one end in a lip, wherein the end of said graft vessel is everted over the distal surface and at least a portion of the proximal surface of the lip of the first structural means; and (c) sliding said second structural means over the tubular region of said first structural means in a manner sufficient to stably attach said graft vessel to said host vessel and establish fluid communication between the lumens of said graft and host vessels; whereby said end-to-side anastomosis is performed (Column 14 lines 15-53).

Regarding claims 23-24, Kaster discloses that wherein said graft vessel is prepared by: sequentially inserting said graft vessel through the tubular regions of said first and second structural means; and everting the end of said graft vessel over the distal surface and at least a portion of the proximal surface of the lip of said first structural means (FIG. 9 and Column 14 lines 15-53).

Regarding claim 29, Kaster discloses that said kit further comprises a delivery means (Column 11 lines 37-66).

Regarding claim 30, Kaster discloses that said kit further comprises a structural means holder for use in preparation of a graft vessel (ringflange 54).

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***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster in view of U.S. Patent No. 6,007,576 to McClellan.

Kaster discloses the claimed invention except for the kit comprising a plurality of anastomosis systems. McClellan teaches that an anastomosis system may be provided in a variety of sizes in order to accommodate different sizes of vessels (Column 8 lines1-8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the kit of Kaster with a plurality of sizes in order to be able to supply systems for different vessel sizes.

***Response to Arguments***

8. Applicant's arguments with respect to claims 1, 2, and 4-30 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter  
Examiner  
Art Unit 3731

*jrb*  
jrb

*Julian W. Woo*

**JULIAN W. WOO**  
**PRIMARY EXAMINER**